

Study Identification

Project Title: Safety/Efficacy of Intranasally-Administered Bioactive Factors Produced by Autologous M2 Macrophages in Patients With Organic Brain Syndrome

Brief Title: Intranasal Inhalations of Bioactive Factors Produced by M2 Macrophages in Patients With Organic Brain Syndrome

The protocol was approved by the Ethics Committee of the Institute of Fundamental and Clinical Immunology (approval no 92, 11/10/2015).

October 11, 2015

Statistical Analysis Plan

Data will be analyzed using Statistica 6.0 software for Windows (StatSoft Inc. USA). The results of statistical analysis will be presented as median (Me) and interquartile range (IQR; LQ-UQ). To check the normality of the distribution of data, the Kolmogorov-Smirnov test and the W Shapiro-Wilk test will be used. To assess the significance of differences, Fisher's exact test (for discrete variables) and the non-parametric Mann-Whitney test (for continuous variables) will be used. Spearman's rank correlation coefficient (R_s) will be used to measure the statistical dependence between two continuous variables. Differences with p less than 0.05 will be considered statistically significant.